Cost-sharing and adherence, clinical outcomes, health care utilization, and costs: A systematic literature review

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What is already known about this subject

- Patient out-of-pocket health expenditures have increased over the past decade because of rising health care costs and evolving benefit designs.
- Prior systematic reviews found higher levels of cost-sharing negatively affect prescription drug adherence.

What this study adds

- This systematic literature review provides a contemporary review of the available evidence regarding costsharing and 4 outcomes (medication adherence, clinical outcomes, health care resource utilization, and health care costs).
- We describe the relationship between higher cost-sharing and outcomes (worse, no difference, or better) and factors that influence this relationship.
- When designing plan benefits and costsharing, a holistic view of cost-sharing and clinical and economic outcomes should be considered.

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ABSTRACT

BACKGROUND: US health plans are adopting benefit designs that shift greater financial burden to patients through higher deductibles, additional copay tiers, and coinsurance. Prior systematic reviews found that higher cost was associated with reductions in both appropriate and inappropriate medications. However, these reviews were conducted prior to contemporary benefit design and medication utilization.

OBJECTIVE: To assess the relationship and factors associated with cost-sharing and (1) medication adherence, (2) clinical outcomes, (3) health care resource utilization (HRU), and (4) costs.

METHODS: A systematic review of literature published between January 2010 and August 2020 was conducted to identify the relationship between cost-sharing and medication

adherence, clinical outcomes, HRU, and health care costs. Data were extracted using a standardized template and were synthesized by key questions of interest.

RESULTS: From 1.995 records screened. 79 articles were included. Most studies, 71 of 79 (90%), reported the relationship between cost-sharing and treatment adherence, persistence and/or discontinuation; 16 (20%) reported data on cost-sharing and HRU or medication initiation, 11 (14%) on costsharing and health care costs, and 6 (8%) on cost-sharing and clinical outcomes. The majority of publications found that, regardless of disease area, increased cost-sharing was associated with worse adherence, persistence, or discontinuation. The aggregate data suggested the greater the magnitude of cost-sharing, the worse the adherence. Among studies examining clinical outcomes, cost-sharing was associated with worse outcomes in 1 study and the remaining

3 found no significant differences. Regarding HRU, higher-cost-sharing trended toward decreased outpatient and increased inpatient utilization. The available evidence suggested higher cost-sharing has an overall neutral to negative impact on total costs. Studies evaluating elimination of copays found either decreased or no impact in total costs.

conclusions: The published literature shows consistent impacts of higher cost sharing on initiation and continuation of medications, and the greater the cost-sharing, the worse the medication adherence. The evidence is limited regarding the impact of cost-sharing on clinical outcomes, HRU, and costs. Limited evidence suggests increased cost-sharing is associated with more inpatient care and less outpatient care; however, a neutral to no difference was suggested for other outcomes. Although increased cost-sharing is intended to decrease total costs, studies evaluating

reducing or eliminating cost-sharing found that total costs did not rise. Today's growing cost-containment environment should carefully consider the broader impact cost-sharing has on treatment adherence, clinical outcomes, resource use, and total costs. It may be that cost-sharing is a blunt, rather than precise, tool to curb health care costs, affecting both necessary and unnecessary health care use.

Increasing the share of health care costs for which beneficiaries are responsible is a strategy aimed at reducing the use of unnecessary health care goods and services and, ultimately, decreasing total health care costs. It is reasoned that cost-sharing will compel consumers to be more thoughtful and selective in their health care choices if they are required to shoulder a greater burden for such services. Cost-sharing was first examined 50 years ago in the RAND Health Insurance Experiment (HIE)1 in which it was found that increased cost-sharing decreased health care utilization and prescription drug use.² Results from the HIE also suggested that decreased health care utilization and medication use did not impact health outcomes. However, an exception to this was found for an important demographic: the poorest and sickest participants. Since that landmark study, health care insurance options and plan designs have continued to evolve and the cost of health care, health premiums, and consumer cost-sharing have risen.

Patients seeking care pay out-of-pocket (OOP) expenditures (through plan deductibles, copays, or coinsurance) and this cost-sharing has increased substantially over time. Between 2005 and 2016, in employee-sponsored US health insurance plans, the annual deductible increased by 59% for beneficiaries with single coverage.3 Cost-sharing for medications has grown from 1 or 2 medication tiers to 3 or 4 tiers with wider cost-sharing differences (eg, on average \$11 for tier 1, \$35 for tier 2, \$62 for tier 3, and \$116 for tier 4).4 Beyond typical formulary copays, coinsurance for specialty medications is common with patient contributions averaging 26% in 2020.4 In 2018, the average family in a large-employer plan paid more than \$3,000 in OOP costs annually on top of \$5,000 in premium costs.⁵ Notably, the increase in OOP and premium costs were disproportionate to wage increases and inflation⁵ such that for many households, OOP health care costs consumed 10% or more of their annual income.6

Previous systematic reviews have found that higher levels of cost-sharing negatively affect prescription drug adherence.7-9 Additionally, individual studies have suggested that poor medication adherence correlates with increased disease complications, 10,11 hospitalizations, 12,13

mortality,13 and health care costs.14 In a 2007 systematic review, the use of medical (nonpharmacy) services increased with greater prescription cost-sharing for certain clinical conditions.7 Thus, although insurers and employers view cost-sharing as a means to control costs,15 high cost-sharing may paradoxically increase health care costs if it leads to poorer disease control and, ultimately, greater health care utilization and costs.

A systematic review of the published cost-sharing literature has not been recently undertaken. This systematic literature review (SLR) was conducted to answer the following questions: (1) Does the literature address the relationship between cost-sharing and treatment use, clinical outcomes, health care utilization, and health care costs? (2) What is the relationship between increased cost-sharing and outcomes (eg, worse outcomes, no difference, or better)? (3) What factors influence this relationship? For example, does the relationship differ by the type of cost-sharing (eg, copays, coinsurance, deductibles), the magnitude of cost-sharing (eg, \$5, \$50, or \$250), or by disease or clinical condition?

Methods

This SLR was conducted according to best practices (ie, Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidance¹⁶) with the SLR methodology defined a priori in a study protocol. Embase and MEDLINE (via Embase.com) were searched (Supplementary Table 1, available in online article) for white papers or peer-reviewed, English-language articles published from January 1, 2010, to August 18, 2020, and reporting results from observational studies or randomized controlled trials (RCTs) conducted in the United States. Included studies met the following criteria: included individuals of any age with health insurance other than Medicaid or Veteran's Administration coverage and reported results on the association between cost-sharing and at least 1 of the 4 outcomes of interest, (1) treatment use (eg, drug adherence, persistence, or discontinuation); (2) disease control, morbidity or mortality; (3) health care resource utilization (HRU; including inpatient services, emergency department [ED] visits, ambulatory care, or medication initiation); or (4) health care direct costs (total health care, medical, or pharmacy costs). Costsharing was required to be reported in monetary amounts. Studies including patients with health insurance coverage solely through Medicaid or Veterans Affairs were excluded because of low or zero cost-sharing. Studies focused on cost-sharing for diagnostic tests or medical care, rather than prescription medications, were also excluded.

Abstracts and full-text documents were evaluated for eligibility by 2 independent reviewers, with any discrepancies resolved by a third reviewer. Data from the included articles were entered into a Microsoft Excel template developed for the SLR; all data were validated by a second researcher. Extracted data included published study characteristics (eg, study design, data source, and time period), study sample characteristics (eg, patient population, clinical conditions, and type of health insurance coverage), and outcomes of interest (eg, publication's outcome definition, relationship to cost-sharing). Information regarding the type and magnitude of cost-sharing (eg, differences in deductibles, differences in copays either due to tiering, the elimination of copays, reductions through copay coupons, or differences in coinsurance amounts) were also extracted. Quality assessment of each study was conducted using a risk-of-bias tool appropriate for the study design.¹⁷⁻²⁰ Data were quantitatively and qualitatively synthesized to address the SLR study questions. Adherence and clinical outcomes were categorized as "worse," "no difference," or "better" based on the association with increased cost-sharing (eg, "worse" indicates that increased cost-sharing is associated with statistically significantly poorer adherence or clinical outcomes) (Supplementary Table 2). Some studies originally reported the effect of decreased cost-sharing; for categorization, their results have been transformed for simplicity. Some studies reported both significant and nonsignificant results within an outcome category. If at least 1 result was significant, the study was categorized as having a significant association. For adherence, persistence, and discontinuation outcomes, in which this issue was the most common, these multiple results were consistently in the form of assessing multiple levels of cost-sharing in which higher levels of cost-sharing reached significance and lower levels did not. In figures that report specific study results rather than an overall categorization, significant and nonsignificant results are reported separately.

Results

OVERVIEW OF INCLUDED PUBLICATIONS

A total of 1,995 citations were screened (Figure 1), and 79²¹⁻⁹⁹ articles met the predefined inclusion criteria (Supplementary Table 3). Most articles (71 of 79, 90%) reported results from retrospective cohort studies, 5 (6%) from RCTs, 2 (3%) from cross-sectional studies, and 1 article reported results from a prospective cohort study. Of the 5 articles reporting results from RCTs, 3 of the publications came from the same trial (the Myocardial Infarction Free Rx Event and Economic Evaluation [MI FREEE] trial). The remaining 2 were from the Affordability and Real-World Antiplatelet Treatment Effectiveness After Myocardial Infarction Study. Most

publications were based on administrative claims analyses; the mean sample size across studies was 652,920 (range: 131-27,269,026). Nearly 80% of studies included individuals covered by commercial insurance, whereas 43% included publicly insured individuals (insurance type was not mutually exclusive, as studies often included >1 type of coverage).

Across publications based on claims databases, a large number of plans and plan designs were included. Specific cost-sharing elements (eg, high-deductible, copay levels) varied even within a publication. However, in terms of the analyses conducted across studies, different copay levels were most often the cost-sharing factor evaluated (eg, the effect of a \$0 copay, association between varying levels of copay amounts, etc). Cost differences ranged from a \$2.65 difference in copay up to a greater than \$3,000 difference in annual OOP costs.

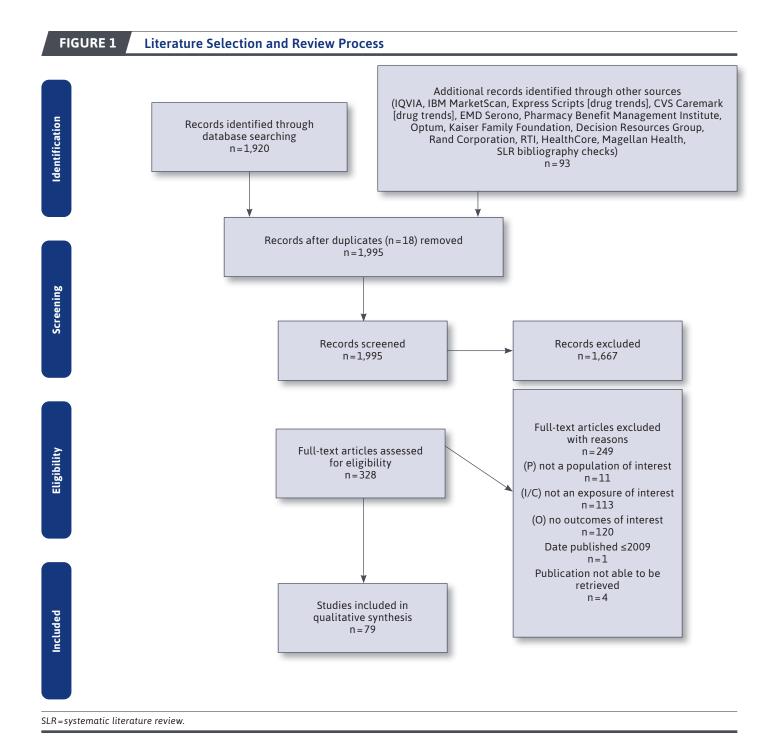
Across the studies, a majority reported data on cost-sharing and adherence (71 of 79, 90%). Fewer studies addressed the additional review questions; 16 (20%) reported data on cost-sharing and HRU or medication initiation, 11 (14%) on cost-sharing and health care costs, and 6 (8%) on cost-sharing and clinical outcomes.

COST-SHARING AND DRUG TREATMENT ADHERENCE, PERSISTENCE, AND DISCONTINUATION

Of the 71 articles reporting data on the relationship between cost-sharing and treatment adherence, persistence, and/or discontinuation, adherence was the most commonly reported outcome. Adherence outcomes were reported in 63 of 71 (89%) publications; persistence and discontinuation were each reported in 19 of 71 (27%) articles.

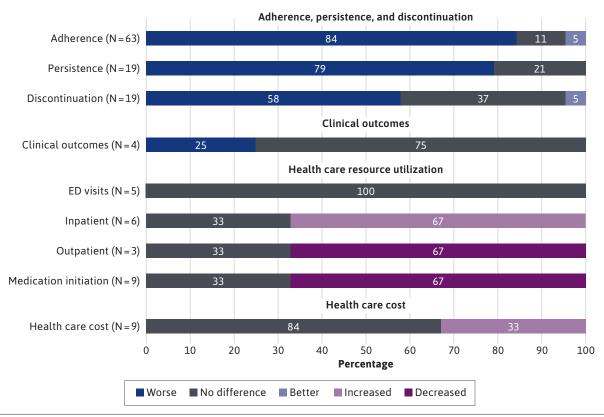
Despite heterogeneity in disease, study design, patient characteristics, and outcome definition, the relationship between higher OOP costs and adherence, persistence, and discontinuation results was relatively consistent across included studies. The majority of publications found that increased cost-sharing was associated with worse adherence (84% of studies), persistence (79% of studies), or discontinuation (58% of studies) (Figure 2). This finding was generally consistent across disease areas (Supplementary Table 4).

When taken together, the included studies appear to suggest not only that increased cost-sharing is associated with decreased adherence but also that there is a "dose-response" relationship, in which larger differences in cost-sharing were associated with worse adherence (Figure 3, <u>Supplementary Figure 1</u>). Similarly, increased cost-sharing was associated with more patients discontinuing treatment (<u>Supplementary Figure 2</u>).



The effect of increased cost-sharing may differ by disease. Although most disease areas were not studied frequently enough to identify trends, results among oncology, diabetes, and cardiovascular diseases were each reported in at least 15% of articles reporting on adherence. The relationship between cost-sharing and adherence appears to be somewhat stronger in studies in which patients are being treated for cardiovascular disease, compared with patients receiving oncology or diabetes treatments.

FIGURE 2 Relationship Between Increased Cost-Sharing and Outcomes of Interest



ED = emergency department.

COST-SHARING AND CLINICAL OUTCOMES

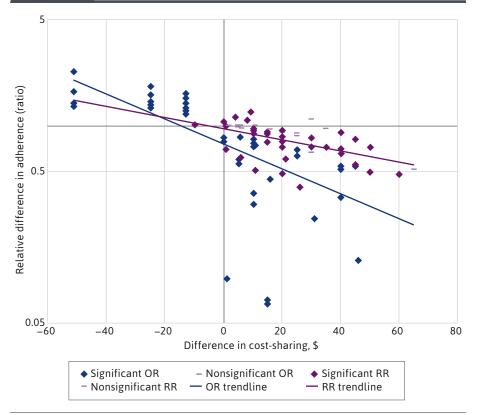
Data on the association between cost-sharing and clinical outcomes were reported in 6 articles, 32,60,89,90,92,94 representing 4 unique studies (the results of the MI FREEE trial were reported in 3 articles, 89,90,92). Across the 4 studies, cost-sharing was evaluated as either the effect of copayment removal (n=3) or copayment differences (n=1; ie, <\$50 vs \geq \$50) (Supplementary Table 5).

A significant association between higher cost-sharing and worse clinical outcomes was found in only 1 of the 4 studies (the MI FREEE trial) (Figure 2). In that study, copay elimination for patients discharged from the hospital following myocardial infarction had statistically significantly fewer major vascular events, revascularizations, or strokes compared with patients with usual cost-sharing (eg, <\$25).89 Additional analyses and subgroup analyses found that the significant reductions in clinical outcomes were specific to non-White patients (Black or African American; Hispanic;

American Indian or Alaska Native; Asian, native Hawaiian, or other Pacific Islander; and ≥2 races). The study authors noted that "because the numbers in specific race and ethnicity categories were small, patients were classified as being white or nonwhite so that there would be enough statistical power to detect clinically meaningful effects."89,90,92

The other 3 studies found no significant association between cost-sharing and clinical outcomes. One study compared the use of copay vouchers vs standard copayments (median monthly voucher value of \$137) for blood thinners with respect to major adverse cardiovascular events. The second study compared eliminating copays vs standard copay amounts (eg, \$10 for generics, \$25 for preferred brands, and \$50 for nonformulary treatments) for diabetes treatments on blood sugar levels at 1 year. The third study compared lower vs higher monthly copays (<\$50 vs ≥\$50) for HIV preexposure prophylaxis and found no statistically significant differences in kidney function markers.

FIGURE 3 Relative Change in Adherence by Change in Cost-Sharing



When the cost-sharing amount was reported as a range, the change in cost-sharing was determined by calculating the difference in the minimums of the 2 categories. For example, when comparing \$6-\$15 with \$0-\$5, the change in cost-sharing would be \$6. Similar trends were identified when the change in costsharing was calculated using the difference in the maximums of the 2 categories. Adjusted estimates were used when they were reported in the original study. If the study reported nonadherence, the inverse of the ratio is plotted here. The observations on this graph are not all independent; several studies provided multiple data points (eg, compared several different levels of cost-sharing to a single reference category). OR = odds ratio: RR = relative risk

COST-SHARING AND HRU

The association between cost-sharing and HRU was reported in 7 studies.32,44,49,52,69,71,78 In 4 of those studies, cost-sharing was evaluated as a difference in copay amount (eg, \$10 vs 50 copay, mean copays of \$30 vs \$54, and copay percentiles ranging from \$100 to \$190).44,49,69,78 In 2 studies, HRU following a copay reduction (eg, \$0 copay or lower copays as part of a value-based insurance benefit) was reported.32,52 Finally, 1 study compared HRU between patients with lower vs

higher annual deductibles (eg, <\$5,000 or >\$5,000)⁷¹ (Supplementary Table 6). Studies evaluated various utilization: inpatient hospitalizations (6 studies), outpatient care (3 studies), and ED visits (5 studies).

The relationship between higher cost-sharing and HRU was specific to the type of utilization evaluated. Four of the 6 studies evaluating hospitalization use found increased cost-sharing was statistically significantly associated with increased hospitalizations. 32,44,49,52,69,78 In 2 of the

3 studies^{44,69,71} in which outpatient care was assessed, increased cost-sharing was statistically significantly associated with fewer ambulatory visits. In contrast, none of the 5 studies that assessed cost-sharing and ED visits found a statistically significant association (Figure 2). 32,44,49,52,69

The association between costsharing and medication initiation was examined in 9 studies (Supplementary Table 7).39,54,59,64,65,69,71,85,99 Two studies evaluated contraception uptake after the removal of copays, afforded by the Affordable Care Act, and did not find that removing copays increased contraception initiation.^{54,64} The remaining 7 studies looked at the association between increased costsharing (assessed as >\$29 copays vs ≤\$29; a \$10 increase in copay; ≥\$1 vs no copay; or maximum annual OOP costs of ≤\$3,000 vs >\$3,000; an HMO plan vs high-deductible health plan benefit design, and a low-deductible vs high-deductible health plan) and medication initiation or vaccinations. Among those 7 studies, 6 found that increased cost-sharing was associated with decreased initiation. 39,59,65,71,85,99

COST-SHARING AND HEALTH CARE COSTS

The association between cost-sharing and health care costs was reported in 11 articles (9 studies; 3 articles report data from the MI FREEE trial).23,25,29, ^{32,44,49,52,78,89,90,92} The costs considered included pharmacy (7 studies), medical (5 studies), and total health care (4 studies), as well as the payment perspective (insurer/plan-paid vs patient paid) (Supplementary Table 8). Three of the 9 studies found significant associations between increased costsharing and higher health care costs.

Seven studies evaluated the association between cost-sharing and patient- and plan-paid pharmacy costs. Most (5 of 7) studies evaluated changes in cost-sharing for diabetes and cardiovascular treatments. The evidence suggests that reduced patient OOP costs are associated with lower patient pharmacy OOP costs, increased plan-paid pharmacy costs, and a neutral effect on total pharmacy costs in most but not all studies. For example, broader Medicare Part D coverage providing lower overall patient OOP costs increased Medicare-paid pharmacy costs.23 In a second study, increasing copays from \$10 to \$50 decreased insurerpaid prescription costs.78 However, coupons did not affect patient or plan-paid pharmacy costs in the third study.²⁹ Finally, lowering OOP costs through the elimination of copays (n = 2),32,52 and removal of copays for patients switching to generics (n=2),25,89,90,92 or through a value-based insurance design had improved employer costs in 1 study, had no difference in total pharmacy costs in 2 studies, and worse (eg, higher) pharmacy costs in a fourth study.

Of the 5 studies that reported on the association between cost-sharing and medical costs, the results were mixed. One study found that increased cost-sharing (raising prescription costs from \$10 to \$50) was associated with increased hospitalization costs.⁷⁸ A second study found no difference in hospitalization costs between low vs high annual OOP medication costs.⁴⁹ Similarly, 2 studies that evaluated the elimination of copays found no significant change in plan total medical costs.^{32,89,90,92} Finally, 1 study that compared copay reductions plus nurse counseling with a control group of usual care without copay reductions, found that higher OOP costs for the control group were associated with higher overall medical costs.⁵²

Overall, 4 studies evaluated the impact of cost-sharing on total health care costs. One study found the inclusion of Medicare Part D coverage (resulting in lower OOP costs) did not affect total health care costs. Similarly, 2 additional studies found higher cost-sharing (eg, \$10 copay increase in 1 study or the effect of copay removal) found no impact on total health care costs. Similarly, 2 additional studies found higher cost-sharing (eg, \$10 copay increase in 1 study or the effect of copay removal) found no impact on total health care costs, with a fixed copay being associated with greater adjusted mean total health care costs compared with coinsurance. The evidence suggests that increased patient cost-sharing, although associated with decreased insurer-paid pharmacy costs, has an overall neutral to negative (ie, increased payer costs) effect on total health care costs.

Discussion

In this SLR, we sought to understand if the published literature provided answers to the questions of whether cost-sharing for prescription drugs was associated with medication adherence, clinical outcomes, health care utilization, and costs. We found a consistent inverse relationship

between cost-sharing and worse adherence across many studies. Higher cost-sharing was consistently associated with lower adherence to prescribed medication. The association persisted regardless of the condition/patient population under study or type of cost-sharing (eg, copays, coinsurance, deductibles). The aggregate data also suggested that larger increases in cost-sharing were associated with worse adherence. The aggregate data suggest that increased cost-sharing may be associated with decreased outpatient visits but increased hospitalizations and no association with ED visits. Thus, the evidence found in this review support a hypothesis that there is an association between increased cost-sharing and prescription adherence and outpatient care, which in turn could be associated with increased hospitalizations. Missing from this hypothesized relationship was an association between increased cost-sharing and poorer clinical outcomes. We found very limited published data on cost-sharing and clinical morbidity, and of the studies found, most did not report a statistically significant association. Overall, increased costsharing did not appear to decrease health care costs.

The relationship between cost-sharing and adherence found in this SLR is consistent with that found 50 years ago in the HIE. Additionally, the results in this review regarding prescription abandonment and adherence with the magnitude of the effect differing by the clinical condition were consistent with those of previous reports. For example, Doshi³¹ found initiation of specialty drugs for cancer was less sensitive than for other conditions such as rheumatoid arthritis or multiple sclerosis. We also found that increased cost-sharing was associated with a lower likelihood of initiating treatments. Likewise, the HIE found that cost-sharing had a greater effect on initiation of health care services than it did on the continuation of services.² Although we found only limited data linking cost-sharing to disease morbidity, an analysis conducted by the National Bureau of Economic Research (published after the searches were completed for this SLR) found that increased OOP prescription costs both decreased adherence and increased mortality. 100 Notably, the Congressional Budget Office estimated that for every 10% increase in prescription medication use, Medicare spending on medical services is reduced by 2%.101

Cost-sharing is not only intended to lower costs of payers and employers by apportioning part of pharmacy and HRU expenditures to the beneficiary, but also to lower health care costs overall by addressing the "moral hazard" in health care behavior. That is, if patients are aware of and responsible for the costs associated with medications and health care services, they may be more selective in their choices (opting out of treatments with little evidence of effectiveness and choosing less expensive prescription

drugs when given a choice). However, the evidence in this review suggests that patients fail to start and continue therapies based on cost burden alone. Critics of cost-sharing submit that patients will not rationally dissect the pros and cons of different treatments in the face of emergencies, nor will they second guess a doctor's prescribed treatment, and that the disconnect between health care prices vs actual costs complicates patients' ability to compare different available therapies. ¹⁰² It has been posited that the moral hazard theory is ill-suited for health behaviors and that it is a flawed proposition that insurance affords patients additional capital to use superfluous health care. ¹⁰²

A paradoxical effect of cost-sharing is that it may ultimately increase health care costs because patients waive essential health care, which in the long-term results in poorer health and therefore necessitates medical treatments, utilization, and procedures that may have been avoided.102 The limited data we found suggested that cost-sharing does not result in the intended goal of reducing overall health care costs. In most studies, increased cost-sharing had a neutral impact, neither increasing or decreasing health care costs, whereas being associated with poorer health care outcomes. In select studies, there was evidence of higher medical costs being associated with higher patient cost-sharing. For example, Snider⁷⁸ found that higher copays were associated with significant reductions in pharmacy costs but greater hospitalization costs and total costs. Kim⁵² found that medical costs were significantly lower following a value-based insurance design copay reduction, despite higher pharmacy costs. In terms of clinical outcomes, the MI FREEE trial found that removal of medication copays was associated with some decrease in important cardiovascular events; no significant association was found between cost-sharing and clinical outcomes in 3 other studies of different patient populations. In terms of health care utilization, the limited published evidence suggests that higher cost-sharing was associated with greater inpatient and lower outpatient utilization and no association with ED visits.

LIMITATIONS

The limitations associated with this review and the relationship between cost-sharing and outcomes are many. First, our review was limited to published studies. Results from abstracts and unpublished results were not included. Second, we used a broad definition for cost-sharing. The type (eg, deductible, coinsurance, and copay) and magnitude (eg, \$5, \$50, or >\$5,000 deductible) of cost-sharing were not homogenous. Third, the outcome definitions varied (eg, the proportion of days covered, medication possession ratios, or specific thresholds for treatment adherence, etc),

making comparisons across publications difficult. Fourth, the association between cost-sharing and outcomes may be differentially affected by the specific health condition a patient has, by insurance population (eg, Medicare Part D vs commercial or high-deductible health plans), or by patient characteristics, ¹⁰³ including income, health status, and race and ethnicity, each of which has been shown to be related to overall health care use and other factors.

In the commercial market, certain benefit designs seek to lower cost-sharing for some or all patients. For example, a recent Internal Revenue Service rule allows certain employer-sponsored high-deductible health plans to offer an expanded list of preventive medications at a lower or no cost prior to satisfying the plan deductible. Other benefit designs, including several in this review, aim to reduce or eliminate copays for high-value services. As others have hypothesized, the benefits of reducing or eliminating for select services may not have an equal but opposite impact on health care service use. Tools such as these move from cost-sharing as a blunt tool to a nuanced approach to encourage high-value care.

POLICY IMPLICATIONS

In the public policy dialogues, many recognize that OOP costs can be burdensome. In the Medicare prescription drug program, the Low-Income Subsidy limits cost-sharing for those who are at less than 150% of the federal poverty level. For those under less than 135%, the most they would pay for a brand product in 2021 is \$9.20¹⁰⁴; however, for those who do not qualify for this subsidy, catastrophic coverage is only permitted after paying \$6,550 in prescription drugs. Recent discussions in Congress surround implementing an annual OOP cap, with the potential for "smoothing," which could spread the cost of the annual OOP over the course of many months, with a cap in monthly spending.¹⁰⁵

The connection between OOP and patients is appreciated by a number of states. Some states have implemented patient protections for certain plans to include no deductible for prescription drugs or capping the amount per month in OOP drug costs. Unlike the conditions most frequently studied in this review (eg, cardiovascular, diabetes), most states address OOP costs associated with specialty medications. A recent publication evaluated 3 states that capitated OOP costs for specialty medications and found lower beneficiary costs without raising total health care spending. 106

Conclusions

Cost-sharing was developed to reduce unnecessary use of health care services and reduce total health care spending. The published literature shows a consistent impact of higher cost-sharing on initiation and continuation of medications, and the greater the cost-sharing, the worse the medication adherence. The evidence is more limited regarding the impact of cost-sharing on clinical outcomes, resource use, and total health care costs. Although the limited published evidence suggests that higher costsharing was associated with greater inpatient and lower outpatient utilization, it also suggests a neutral to no difference in other outcomes. Today's growing environment of health care cost-containment should carefully consider the broader impact costsharing has on treatment adherence, clinical outcomes, resource use, and total health care costs. It may be that cost-sharing is a blunt, rather than precise, tool to curb health care costs, affecting both necessary and unnecessary health care use. Findings from the decades-old HIE hold today.

DISCLOSURES

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